Accredited testers

Issued February 2023

EPA 1138/23: The Radiation Protection and Control (RPC) Act 2021 was assented to on 11 February 2022 and the subsequent Radiation Protection and Control (RPC) Regulations 2022 was published in October 2022. Changes to the legislation reflect a move toward national uniformity in radiation protection to meet current practices and standards.

1 Introduction

The legislation will be implemented on 11 February 2023, along with the introduction of seven EPA codes of compliance that further define the specifics of regulatory requirements in relevant areas of practice. The legislation is further supported by related ARPANSA codes listed in the RPC Regulations.

Some changes to the radiation protection regulation will be phased in following introduction of the new legislation. This includes:

- Reform of the registration process for X-ray apparatus and introduction of critical failure limits to some compliance tests for X-ray apparatus.
- Changes to conditions attached to Licences to possess and Licences to operate.

2 Codes

As per Regulation 30 of the RPC Regulations under the RPC Act, a radiation source must comply with the provisions of a relevant code (outlined in Schedule 2 of the Regulations) that are expressed as mandatory provisions applying in respect of the radiation source.

Much of the technical detail outlined in the *Radiation Protection and Control Regulations 2015* has been removed from the 2022 regulations allowing for a more responsive approach to regulating radiation safety as technology evolves. The technical detail now resides in codes that can be updated with greater ease.

Codes affecting the regulatory obligations of medical diagnostic X-ray apparatus are:

Code 2: Code of Compliance for facility design and shielding 2022 − Provides the mandatory requirements for radiation apparatus, including diagnostic imaging apparatus used for medical, chiropractic or veterinary purposes, dental cone beam CT, radiotherapy apparatus and non-medical apparatus. This code does not apply to plain dental or panoramic/cephalometric apparatus as their shielding requirements are stipulated in the Dental Code.

Rather than exposure rate limits for areas outside shielding to X-ray apparatus rooms, the new code requires the shielding design and verification methods of either the NCRP 147 or BIR 2012 to be used. A consequence of this means new dose constraints to workers and the public are required by the code. Effective dose to workers must not be greater than 5 (milliSievert) mSv/year, and for the public not greater than 1 mSv/year

Code 3: Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022 − Provides the mandatory radiation safety requirements for fixed, mobile, and portable apparatus used or designed to be used for, mammography or soft tissue radiography, medical or veterinary computed tomography, medical or veterinary fluoroscopy, medical, veterinary or chiropractic plain radiography and medical X-ray absorptiometry.

Code 4: Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022 − Provides the mandatory requirements for the dental modalities and the shielding requirements for plain dental and panoramic/cephalometric apparatus.

Code 7: Code of Compliance for labelling and signage of ionising radiation sources 2022 − Applicable to the labelling and signage requirements of all X-ray apparatus.

3 Test protocols

There are eight new test protocols derived from their relevant codes which describe the requirements of testing for regulatory compliance of X-ray apparatus:

- Dental – Plain radiography (intra oral).
- Dental – Panoramic & cephalometric.
- Dental – Cone beam CT.
- Medical, veterinary & chiropractic – Plain radiography.
- Medical, veterinary & chiropractic – Shielding.
- Medical & veterinary – Computed tomography.
- Medical & veterinary – Fluoroscopy.
- Mammography.

Changes in the new protocols are to bring apparatus testing requirements into line with national codes. Testing requirements for medical apparatus are derived from the EPA Code 3. This Code has been developed to align with the ARPANSA draft *Multi-jurisdictional Radiation Apparatus Testing Requirements*. As this is a draft document, any future changes will be monitored for how this may affect EPA Codes and test protocols in the future.

Changes to test protocols include changes to the limits for testing plain dental apparatus with a reduction in tube leakage rate to 0.25 mGy/h. As mentioned in EPA Code 2, shielding design and verification will require the use of either the NCRP 147 or BIR 2012 methods and this is required in the test protocols.

4 Dose constraint

The new concept of constraints has been introduced in the EPA Code of Compliance for facility design and shielding 2022 to design and assess optimisation of protection.

Design constraints under planned exposure situations are:

1 For occupational exposure of a worker:

   a not greater than an effective dose of 5 mSv in a year; or

   b not greater than an effective dose approved by the Minister and documented in an approved radiation management plan; and

2 For exposure of any other person, not greater than an effective dose of 1 mSv in a year.

5 Cyclic testing

Cyclic testing involves the complete compliance assessment of X-ray apparatus used for human diagnostic purposes at regular intervals to ensure the radiation safety and performance of the apparatus continues to comply over time. It will be

the owner's responsibility to engage testers to ensure the ongoing compliance of X-ray apparatus with regulatory requirements.

Cyclic testing for the regulatory compliance of radiation apparatus is applicable to fixed, mobile and portable diagnostic X-ray apparatus used on humans only. The cyclic testing will be introduced in South Australia in a staged approach as listed in the following table.

As an example, any CT apparatus installed, and compliance tested prior to February 2024 will have its first cyclic compliance testing performed from February 2024 until February 2026. Cyclic testing will then need to be completed every two years from that date. If a new CT apparatus is installed sometime between February 2024 and February 2026 the due date for the first cyclic testing is two years from the date of initial compliance test when the apparatus was first registered.

Apparatus used or designed to be used for	Frequency of testing	Year of introduction
Computed tomography	2 years	Feb 2024
Fluoroscopy (including apparatus capable of both fluoroscopy and plain radiography)	2 years	Feb 2024
Mammography or soft tissue radiography	1 year	Feb 2025
Plain radiography	2 years	Feb 2025
Dental apparatus	5 years	Feb 2026
X-ray absorptiometry apparatus	5 years	Feb 2026

6 Registration reform

A new process for the registration of ionising X-ray apparatus used for diagnostic purposes will commence on 11 February 2023.

From the commencement date, the owner must have submitted an application to register the apparatus prior to the conclusion of the installation phase and prior to clinical use. Then following an initial assessment, the EPA will issue the owner with a provisional registration.

Owners will be allowed a 60-day period under the provisional registration in which to have regulatory compliance verified. Clinical use is permitted during this 60-day period subject to the terms outlined.

This new process requires that the accredited tester must forward their test report and certificate of compliance, to the owner, rather than the EPA which has previously been the case.

If compliant, the owner must then forward these documents to the EPA within the 60-day period and the apparatus then becomes fully registered with a new condition. The test report and certificate of compliance should be emailed to rpb.compliance@sa.gov.au

If the initial compliance test of the apparatus is found to be non-compliant but the fault not critical, as detailed in the relevant test protocol, the owner is still permitted to operate the apparatus for clinical use but must ensure that the fault is rectified within the 60-day time period and retested by the accredited tester. Incomplete or not fully compliant certificates of compliance should not be submitted to the EPA.

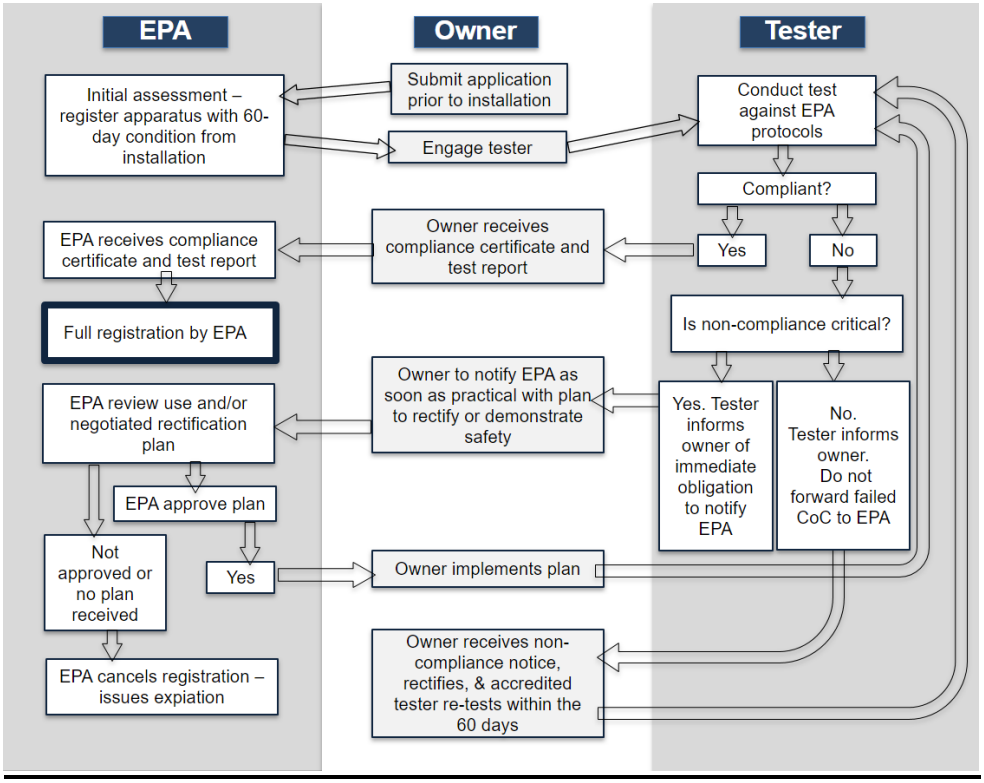
Critical failure limits are introduced on certain tests for medical apparatus where the significance of a non-compliance means the apparatus must not be clinically operated. Where the non-compliance is a critical failure, the tester must

inform the owner who must immediately inform the EPA of the fault and ensure no clinical use of the apparatus is undertaken without the consent of the EPA and a rectification process is agreed to. The EPA should be notified of critical failures at https://ask.your.epa.sa.gov.au/enquiry/. The tester will provide the owner with further precise instructions regarding notifying the EPA of critical faults. Testers will also be required to place signage on the apparatus warning against operation of apparatus due to critical failure.

If at any time the owner expects to not be able to fulfil their obligations to demonstrate apparatus compliance to the EPA within the 60-day allowance period, they must communicate this to the EPA via email and seek approval for further time if warranted.

The 60-day time period from the end of installation will be phased out over the next two years, meaning clinical use of apparatus will not be permitted prior to demonstrating compliance in the form of a finalised certificate of compliance and test report. In preparation of this reform the EPA recommends that an owner demonstrates compliance prior to clinical use. The EPA will continue to consult with licensees regarding the final implementation of this reform.

The following diagram outlines the new process.



7 Public register

Section 77 of the RPC Act requires the Minister to keep a publicly available register of accreditations, authorisations, registrations and permits. Regulation 125 of the RPC Regulations sets out the information to be included on the register.

8 Feedback

The EPA encourages all questions and feedback on the implementation of the new legislation. Please email: EPARadiationProtectionBranch@sa.gov.au

Further information

Legislation

Online legislation is freely available on https://service.sa.gov.au/12-legislation

General information

Environment Protection Authority
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